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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 743,391	04.17.2001	Christine Bernegger-egli	A33847-67425	2379

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BAKER & BOTTS  
30 ROCKEFELLER PLAZA  
NEW YORK, NY 10112

EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 11/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/743,391

Applicant(s)  
Bernegger-egli et al.

Examiner  
Irene Marx

Art Unit  
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Oct 3, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above, claim(s) 10 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO 413) Paper No.'s _____   |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO 152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement s (PTO-1449) Paper No.'s <u>6</u> | 6) <input type="checkbox"/> Other: _____                                    |

The application should be reviewed for errors. Error occurs, for example in the spelling of "serinprotease".

Applicant's election with traverse of Group I, claims 1-9, in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the groups are conceptually linked and no separate search would be required.

However, as noted in the restriction requirement, a common inventive concept is lacking between groups I and II because the compounds of Group II, lack novelty. Therefore, the claimed compounds and the method of making compounds lack those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art. Therefore, a technical relationship is lacking among the claimed inventions involving one or more special technical features.

No common inventive concept is shared among groups I and II, since the claimed method of making is not required to make the compounds of Group II, since the method of group I is not especially adapted for the production of the compounds of group II, and as shown by the cited reference. Therefore, a technical relationship is lacking among the claimed inventions involving one or more special technical features.

Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exists.

Clearly different searches and issues are involved with each group.

For these reasons, the restriction requirement is deemed proper and is adhered to. The restriction requirement is hereby made FINAL. .

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 8-9 are vague and indefinite in the recitation of "in the presence of a nucleophile... and a base", since it is doubted that the mere "presence" of a nucleophile and base is sufficient. It is recommended that the phrase --an effective amount of a nucleophile and a base... to produce the optically active compounds of formulae I and II-- be replaced therefor.

Claims 1-9 are incomplete in the absence of a recovery step for the product produced.

While there is no specific rule or statutory requirement which specifically addresses the need for a recovery step in a process of preparing a composition, it is clear from the record and would be expected from conventional preparation processes that the product must be isolated or recovered. Thus, the claims fail to particularly point out and distinctly claim the "complete" process since the recovery step is missing from the claims. The metes and bounds of the claimed process are therefore not clearly established or delineated.

Claims 1-9 are confusing in the recitation of "general formula". The intended meaning of "general" is unclear in this context, and appears redundant.

Claims 8 and 9 are confusing in the recitation of "is reduced" as the last step, since there is no indication of the process used.

Claims 5-7 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must depend on another claim in the alternative. See MPEP § 608.01(n).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2 and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Csuk *et al.*.

The claims are directed to the hydrolysis of 2-azabicyclo[2,2]hept-5-en-3-one using a hydrolase such as lipase and their subsequent reduction.

Csuk *et al.* teach the hydrolysis of 2-azabicyclo[2,2]hept-5-en-3-one using a hydrolase such as lipase and their subsequent reduction (See, e.g., page 269, last paragraph and page 270).

Claims 1-2 and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakano *et al.*.

The claims are directed to the hydrolysis of 2-azabicyclo[2,2]hept-5-en-3-one using a hydrolase such as lipase and their subsequent reduction.

Nakano *et al.* teach the hydrolysis of 2-azabicyclo[2,2]hept-5-en-3-one using a hydrolase such as lipase and their subsequent reduction (See, e.g., page 2381 and 2384).

Claims 1 and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Evans *et al.* '933..

The claims are directed to the hydrolysis of 2-azabicyclo[2,2]hept-5-en-3-one using a hydrolase such as lipase and their subsequent reduction.

The reference teaches the hydrolysis of 2-azabicyclo[2,2]hept-5-en-3-one using a hydrolase See, e.g., Example 1.

Claims 3 and 4 appear to be free of the art of record.

No claim is allowed.

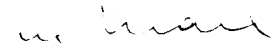
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.

  
Irene Marx  
Primary Examiner  
Art Unit 1651